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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,685	04/22/2005	Einar Moen	Q-84077	4835

23373 7590 05/01/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,685	MOEN ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14 and 25-36* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14 and 25-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The previous Office action mailed by the office on 02/22/2008 is **rescinded** in response to the **supplemental amendment** received by the office on February 20th, 2008, and replaced with the current Office action. The new time period for response has been reset to 3 months starting from the mailing date of this office action.

Claims 11-14 and 25-35 (applicant's originally elected invention of group II) are being examined on their merits, herein.

Election/Restrictions

Newly submitted claim 36 is directed to an invention that is independent or distinct from the invention originally claimed and elected (i.e. the product of group II) for the following reasons:

Newly presented claim 36 is drawn to a **method of using** compositions (i.e. sterile microorganism growth substrate of the invention of group II) for culturing a microorganism (as recited specifically in claim 36). Since, the composition (a sterile microorganism growth substrate as recited in claims 11-14 and 25-35) as claimed is known in the prior art (see the prior art references relied upon in the rejection, below), no special technical feature unites the multiple inventions (products and processes of use) as currently presented by the applicants.

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement is deemed to be proper and is made FINAL.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly added claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 11-14 and 25-35 (applicant's elected invention of group II), as currently amended, are examined on their merits in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 29 (as currently amended) **are/remain** rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention.

The invention appears to employ novel biological material, bacterial strains (such as recited in instant claims 28 and 29). Since the biological materials (i.e. the claimed bacterial strains) are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the biological material. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public.

It is noted that applicant has deposited the biological material (instant specification, page no. 3, second, full paragraph, in particular; and applicant's remarks filed on August 3rd 2006, page 6, last paragraph, in particular), but there is no indication in the specification as to **whether the deposit was made under Budapest treaty**. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material (in the instant case, bacterial strains as recited in the instant claims 28 and 29) has been deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and **address of the depository**, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

Response to Arguments in Supplemental Amendment

Applicant's response (dated 2/20/2008) that crossed in the mail to the 35 USC 112 first paragraph rejection in the form of a supplemental amendment is as follows:

"On page 2 of the Office Action, the Examiner rejects Claims 28-29 under 35 U.S.C. § 112, first paragraph.

Applicants file herewith an appropriate **Statement of Availability**, to thereby render moot this rejection.

In view of the amendments to the claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested."

In response, it is noted that applicant's "statement of availability" for the biological deposit of microbial strains NCIMB 41525, NCIMB 41526, NCIMB 41527 and NCIMB 41528 is duly acknowledged. However, the strains claimed (and disclosed in the instant specification, page 3, 3rd paragraph, in particular) in instant claims 28 and 29 have different NCIMB deposit numbers (which are NCIMB 11132, NCIMB 13287, NCIMB 13288 and NCIMB 13289, respectively), which is presumed to be an error on part of applicants. The response does not provide the basis for such a change in the deposit numbers of said bacterial strains (see applicant's remarks, dated 2/20/08), which is not supported by the original disclosure as filed with the office.

The 35 USC 112, first paragraph rejection as set forth in the previous office action is still valid, and is therefore, maintained hereafter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims11-14 and 25-35 (as currently amended) are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bothe et al (*Appl. Microbiol. Biotechnol.*, 2002; IDS) taken with Norferm, DA (Product brochure, 1998; IDS) and Larsen & Joergensen (*Appl. Microbiol. Biotechnol.*, 1996; IDS), and further in view of Atlas & Parks (Handbook of Microbiological Media, 1993 edition; [U]) and Patz et al (DD 290,917; IDS, an English translation was provided by the office in previous office action).

> Claims (as currently amended) are generally directed to a sterile microorganism growth substrate (i.e. a composition) comprising a sterilized nutrient composition wherein said composition is a sterile biomass generated from bacterial cells comprising at least one methanotrophic bacteria and at least one heterotrophic bacteria, and at least one sterile nutrient, which is a carbon source, added to the biomass, and optionally containing a sterile diluent (see detailed recitation of instant claims 11-14 and 25-35).

Bothe et al (IDS) disclose a composition (i.e. a bacterial biomass) comprising biomass generated from bacterial cells, wherein bacterial cells comprising at least one species of methanotrophic bacteria (such as *M. capsulatus* (Bath) NCIMB 11132) (see Bothe et al, abstract, page 34, materials & methods, in particular; and the disclosure of the protein-rich biomass obtained from said bacterium grown on methane as a carbon source, oxygen, ammonia, and minerals, and water in a reactor, and centrifuged, ultrafiltered, heat-inactivated, and finally spray-dried in the form of a free-flowing, granulated product that is suitable for various applications as a high protein and nutrient source; see Norferm, DA, product brochure, 1998) and at least one species of heterotrophic bacteria (such as *Ralstonia* sp., *Aneurinibacillus* sp., or *Brevibacillus* sp; see Bothe et al, abstract, pages 34, 35 and 38, in particular), at least one sterile nutrient (such as components of nitrate/mineral salts, NMS medium as described by Larsen & Joergensen; cited on page 138, left column, in particular).

However, a sterile microorganism growth substrate comprising a sterile nutrient, which is a carbon source, as specifically recited in claim 11, comprising at least one **sterile nutrient** added to the biomass, such as **glucose**, or a combination of nitrate and mineral salts that is present in a **weight ratio on a dry mass basis** (as specifically recited in instant claims), is not explicitly disclosed by the combined disclosures of Bothe et al (taken with Norferm, DA and Larsen & Joergensen).

Atlas & Parks [U] provide the detailed disclosure about various nutrient media compositions (i.e. sterile microbial growth substrates) routinely used for the cultivation (on solid as well as liquid media) of methanotrophic and heterotrophic bacteria (see Atlas & parks, for various methanotrophic bacteria, pages 574-579; and for heterotrophs such as various lactic acid bacteria and *Lactobacillus* species, pages 483-488, in particular). Atlas & Parks teach the use of **glucose as a sterile nutrient** for use in

various media compositions routinely used for cultivation of various microbial species (see Atlas & Parks, pages 576, 483-488, in particular), and also the use of **nitrate and mineral salts** (see Atlas & Parks, pages 574-575, in addition to the teachings from Larsen & Joergensen, page 138, left column, 1st paragraph, in particular) in the cultivation of microorganisms (being especially useful in the cultivation of methanotrophic bacteria). In addition, Atlas & Parks teach the fact that all the growth media (be it solid or liquid) are customarily autoclaved (or filtered sterilized for heat sensitive materials, such as vitamins, etc.) before use in the preparation of a microbial growth substrate to be useful in the processes of growing or culturing desired microorganisms (see sections on the "Preparation of Medium", page 577, in particular).

Patz et al [U] teach a microorganism growth substrate comprising a sterile nutrient composition (**chemical thermal hydrolysate**; see Patz et al, page 3, substance of the invention, and page 5, first paragraph, and example 1, in particular) obtained from the biomass of a culture of bacteria including methanotrophic bacteria (a methylotrophic bacteria such as *Methylobacterium rhodesianum* IMET 11401; see Patz et al, page 1, claims and page 3, substance of the invention, in particular) further comprising at least one sterile nutrient (such as a carbon source, methanol; see Patz et al, , and optionally containing a diluent (such as water; see Patz et al, example 1 and 2, pages 6 and 7, in particular). Patz et al also teach sterile nutrient medium for fermentation of bacteria containing nitrate and mineral salts and combinations thereof (such as iron, copper, magnesium, manganese, zinc, nickel, boron, calcium, potassium, sodium, cobalt; see Patz et al, page 7, in particular).

Therefore, given the detailed disclosure for the components of the claimed growth substrate composition in the cited prior art references, it would have been obvious to a person of ordinary skill in the microbial art at the time this invention was made to modify the growth substrate (i.e. the biomass) composition of Bothe et al (taken with the disclosures of Norferm, DA and Larsen & Joergensen, as discussed above) such that the growth substrate comprises a sterile nutrient as a carbon source, such as glucose, further contains nitrate and mineral salts, and/or a combinations thereof, as explicitly suggested and disclosed by Atlas & parks [U], and is sterilized in order to be suitable for use as a sterile composition for growth of desired microbes (suggested as a routine step in the preparation of various types of growth substrates).

The person of ordinary skill would be motivated to modify the growth substrate composition comprising the biomass generated from bacterial cultures (as taught by Bothe et al) because the sterile nutrient compositions containing glucose, nitrate and mineral salts have been routinely used in the cultivation of various microorganisms (methanotrophic as well as heterotrophic) as explicitly disclosed by Atlas & parks (see discussion, supra). Furthermore, given the disclosure of Patz et al for the use of a bacterial biomass (a methanotrophic **bacterial hydrolysate** used as a nutrient source; see disclosure above) for cultivation of bacteria, an artisan of ordinary skill in the fermentation art would be highly motivated to use this protein-rich biomass generated from methanotrophic bacteria, as a nutrient source when making a sterile growth substrate composition (for example, a culture medium) suitable for growth of microorganisms.

One of ordinary skill in the microbial art would have had a reasonable expectation of success when modifying the composition according to the disclosures of Atlas & Parks and Patz et al, because the prior art references have explicitly disclosed the amounts, ratios and method of preparation (including method of sterilization, such as autoclaving and filter sterilization) of such sterile growth media/substrate compositions that are useful in cultivation of various microorganisms.

Although, the cited prior art references do not explicitly teach a microorganism growth substrate composition wherein the sterile nutrient such as glucose, or a combination of nitrate and mineral salts are present in specific **dry mass basis** (as recited in the instant claims) in relation to the sterile biomass (obtained from the culture of methanotrophic and heterotrophic bacteria) used in the invention as claimed, such use of specific ratios of required nutrients (alone as well as in combinations thereof) in relation to the biomass used in the composition would have been obvious and routine to a person of ordinary skill in the microbial art (As evident by the fact that the optimum amounts of sterile nutrient such as glucose, and nitrate and mineral salts are explicitly disclosed by the referenced inventions of Larsen & Joergensen, Atlas & Parks and Patz et al; see discussions above). The selection of specific ratios to be used of the nutrient components (in relation to the biomass used) in the claimed growth substrate composition would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that it is a routine procedure to optimized the ratios of ingredients for the culture of any given individual microorganism (relative to other components or nutrients used in the composition) in order to obtain an optimum

growth rate and yield of specific cultured microbial product, or a desired microbial biomass. Furthermore, given the fact that sterile nutrients such as nitrate and mineral salts have been used by Bothe et al (in view of Larsen & Joergensen) in the cultivation of Methanotrophic bacteria (such as *Methylococcus capsulatus* (Bath) strain) using the composition as claimed, it would have been a matter of routine optimization of the medium composition as well as of specific ratios of the sterile nutrient in relation to the biomass used to arrive at an optimum growth substrate composition. Therefore, a holding of obviousness over the cited claims is proper.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the microbial art at the time this invention was made.

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

As per MPEP 2144.06, "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Arguments Over Obviousness rejection

Applicant's arguments with respect to claims 11-14 and 25-35 (as they pertain to the prior art rejection of record) have been considered but are not found to be persuasive for the following reasons of record.

Applicants argue the following (see remarks, page 6, 3rd paragraph, in particular):

> "Initially, Applicants respectfully submit that the Examiner's rejection is one based on hindsight, which is an impermissible basis for issuing a rejection. Applicants respectfully submit that it cannot be considered obvious to include the various components taught by Atlas & Parks or by Patz et al absent realization that the microorganism composition itself described in the primary reference may be suitable for use as a growth substrate (or at least as a component of such a substrate). It is this realization which is at the heart of Applicants' invention.
> As will be clear from the following comments, the primary references merely relate to a process for the preparation of a biomass material. It is this biomass material which, in accordance with Applicants' invention, is then used as a component of a growth substrate for use in cultivating other microorganisms. This growth substrate also contains a suitable carbon source which is essential for microorganism growth. None of the primary references in any way teach or suggest the use of the biomass material for this purpose."

In response, It is noted that 1) Bothe et al in view of Norferm DA and Atlas & parks provide the detailed disclosures for the preparation of an end product, i.e. a protein-rich biomass, generated from methanotrophic bacteria (which are known to grow consistently along with at least one species of heterotrophic bacteria; see disclosure of Bothe et al), which can be further added with sterile nutrients and further sterilized as disclosed by Atlas & parks in order to prepare a sterile growth medium or substrate as currently claimed by applicants; 2) disclosure of cited prior art reference of Patz et al clearly provides a "realization" to an artisan of ordinary skill in the microbial art that the biomass generated from the methanotrophic microorganism itself is suitable for use as a microbial growth substrate (see use of sterilized, chemical thermal hydrolysates in the disclosure of Patz et al, patent claims and page 5 of the translation provided, in particular); and 3) Norferm DA brochure discloses various uses of the protein-rich, heat-

treated, spray-dried, granular biomass generated from the culture of methanotrophic bacteria in a biofermentation process, including its use in food and feed for human and animals such as pig, fish, etc, and further demonstrated the benefits accrued from the addition of said protein-rich bacterial biomass in terms of body weight gain, etc. which would clearly implicate the suitability of said biomass as a growth substrate for various microorganisms, for example, intestinal microbes that reside in animal gut. Moreover, a biomass rich in protein (and that also includes nitrogen, carbon and various other beneficial biological components) would be deemed naturally obvious by an artisan of ordinary skill in the microbial art for its use as a protein, nitrogen, or carbon source (akin to the use of various protein hydrolysates, peptones, etc. in commercial media formulations in the art for growth of various microorganisms), when preparing a suitable microbial growth substrate. Thus, the rejection of record is not based on an improper hindsight, as currently alleged by applicants.

Applicants further argue the following (see page 8, in particular):

> "The disclosure of the primary references relied on by the Examiner is thus limited to the production of the methanotrophic bacterium Methylococcus capsulatus (Bath) and its use in feedstuff or for human consumption. None of these references in any way suggest that the resulting biomass itself may serve as the nitrogen source in a growth medium for the cultivation of other microorganisms, as claimed. In the absence of this knowledge, it could not have been considered obvious to provide a sterile product or to combine such with a sterile carbon source as required by the present claims."

In response, it is noted that applicants arguments were fully considered but were not found to be persuasive because, the invention as claimed, does not require the biomass to serve as "the nitrogen source in a growth medium for the cultivation of other microorganisms" (see instant claim 1, in particular).

Applicants arguments that combination of cited prior art references, especially in view of Atlas & Parks "would merely result in an alternative medium for the cultivation of *Methylococcus capsulatus* (Bath)....and would not yield a product falling within the scope of the claims" is not found to be persuasive because said cited reference of Atlas & Parks is relied upon in the rejection to demonstrate the fact that such combination (such as glucose a carbon source) of components are well known in the art of media formulation. It is noted that instant claims do not require any specific requirement, or for that matter a specific microorganisms for which the "sterile growth substrate" has to be suitable for (see claim 1, as amended). On the other hand, it is a common knowledge in the microbial art that an organic biomass (sterile or not) is generally deemed to be a good source of protein, carbon, nitrogen, and other chemical micronutrients upon which several species of microbes would readily grow, if appropriate conditions for growth are provided. In the absence of any evidence to contrary, further additions (to the sterile, methanotrophic biomass) of carbon source such as glucose, or a sterile diluent, or other required minerals would have been obvious to a person of ordinary skill in the microbial art in view of the disclosures provided by Atlas & Parks.

Applicant's argument that the cited reference of Patz et al "contains no teaching with respect to a combination of methanotrophic and heterotrophic bacteria as recited in Applicants' claims. Applicants' finding that a combination of such bacteria may be used as a "broad spectrum" growth medium which may be suitable for use with unknown microorganisms is in no way obvious from Patz et al.", it is noted that said combination is of methanotrophic and heterotrophic bacteria in the biomass generated from

fermentation of *Methylococcus capsulatus* (Bath) under semi-sterile conditions is clearly disclosed by Bothe et al (see teachings, above). As discussed above, Patz et al disclose the use of a methanotrophic bacterial biomass that has been hydrolysed by chemical and thermal means, and has been found to be suitable for growth of methanotrophic bacteria (see Patz et al, claims and page 5, of the translation provided). The suitability of the claimed composition as a "broad spectrum growth medium", however, is neither required by the limitations of the claims as currently presented, nor fully demonstrated by applicants in the instant disclosure as originally filed with the office (see instant disclosure, Table 1, page 8, in particular).

Since, all the components of the claimed composition are disclosed and/or suggested by the cited prior art references, the obviousness rejection of record is deemed proper, and is therefore, maintained.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 11-14 and 25-35 are/remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30

and 32-35, 37-42 and 44 of copending Application No. 10/504,464 (common inventors, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claims in said co-pending application are also directed to a product-by-process (i.e. a composition), which is derived from a biomass hydrolysate generated from the cultured biomass of a methanotrophic bacterium. Since, the two sets of pending claims are co-extensive in scope, an obviousness-type double patenting rejection is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 11-14 and 25-35 are/remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 13-25 and 27 of copending Application No. 10/504,463 (same inventive entity, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claims in said co-pending application are also directed to a product-by-process (i.e. a composition), which is derived from a biomass autolysate generated from the cultured biomass of a methanotrophic bacterium. Since, the two sets of pending claims are co-extensive in scope, an obviousness-type double patenting rejection is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

In response to the ODP rejection of record, applicants state the following:

> "On page 9 of the Office Action, the Examiner provisionally rejects Claims 11-14 and 25-35 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 30 and 32-34 of pending Application No. 10/504,464. Further, the Examiner provisionally rejects Claims 11-14 and 25-35 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 8 and 13-27 of co-pending Application Serial No. 10/504,463.
> Since these rejections are provisional in nature, no action needs to be taken at this time."

Since, applicants have deferred an appropriate response at the present time, the provisional ODP rejections of record, as discussed above, are maintained.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651